

REMARKS

Applicants have herein amended claims 24-46 and claims 48-51 and cancelled claim 48. No new subject matter is added with these amendments. Support for the amendments is found throughout the application (see, e.g., p. 2, line 29 through p. 3, line 7; p. 6, line 3 through p. 7, line 37), and in the language of the original claims (see e.g., original claims 1 and 17).

Claim Rejections - 35 USC § 112, para. 1

Claims 49 and 50 are herein amended to include the limitation for the second organic solvent as one “having limited miscibility or solubility with water.” In addition, the specific listing of solvents in Table 16 of Ullman’s Encyclopedia which is incorporated by reference in the instant application sets forth common ethers (diethyl ether, dibutyl ether, methyl *tert*-butyl ether) and esters (methyl acetate, ethyl acetate, isopropyl acetate, butyl acetate, isobutyl acetate, ethyl glycol acetate, butyl glycol acetate, cyclohexyl acetate) having limited solubility with water. As such, Applicants respectfully submit that amended claims 49 and 50 meet the requirements of 35 USC § 112, para. 1.

Claim Rejections - 35 USC § 112, para. 2

Claims 24, 25, 36 and 44 are herein amended to correct typographical errors. Specifically, a dash has been added between water and miscible in claim 24; the article “a” has been added before pH in claim 25; and the term “one-third to three-fourth” has been corrected to add an “s” at the end of fourth in claims 36 and 44.

Claim 39 is herein amended to include HMG-CoA reductase inhibitors selected “from the group consisting of lovastatin, pravastatin and mevastatin.” Support for this

amendment is found in the specification on p. 2, line 20 through p. 3, line 7; p. 4, line 3 through p. 9, line 30; p. 10, lines 17-20; and Examples 1-3.

Claims 40 and 51 are herein amended to include a specific listing of solvents in proper Markush form. Specifically, the word “acetate” has been added after the listing of the example alkyl acetates “n-propyl acetate,” ... “n-butyl acetate,” and “isobutyl acetate” (as suggested by the Examiner) and the improper second “and” has been deleted.

Claim 44 is herein amended to properly refer to “said second organic solvent,” thus rendering claim 44 definite.

Claim 46 is herein amended to remove the improper “use” language and to properly recite it as a process claim depending from process claim 40, thereby rendering claim 46 definite.

Additionally, claim 46 is herein amended to include HMG-CoA reductase inhibitors “selected from the group consisting of lovastatin, pravastatin, simvastatin and mevastatin.” Support for this amendment is found in the specification on p. 9, line 36 through p. 10, line 9; p. 10, lines 17-20; and Examples 1-5.

Lastly, claims 24, 34-36, 40, 42-44 and 48-51 are herein amended to re-introduce the limitations regarding the first and second organic solvents. Specifically, the phrase “or water soluble” has been re-inserted in claims 24, 34, 35, 40, 42, 43, and 48-51 for the first organic solvent, and the phrase “having limited miscibility or solubility with water” has been re-inserted in claims 24, 36, 40, 44, and 48-51 for the second organic solvent. Applicants previously removed these phrases in response to a rejection under 35 U.S.C. § 112. Since Applicants feel the use of such terms does not render the relevant claims indefinite, the Applicants feel it is appropriate to restore this language in order for the

claims to correspond to the rest of the specification. These phrases are clearly defined in the original application (see p. 7, lines 1-12) wherein it is stated:

The property of the organic solvent of being either water-miscible or water-soluble, or having a limited miscibility or solubility with water is per se known to the man skilled in the art and is, for example, described in "Ullmann's Encyclopedia of Industrial Chemistry", Vol. A24, 5th edition (1993), pp. 437-505, incorporated herein by reference. In the meaning of the present invention, the term "water-miscible or water-soluble" shall refer to organic solvents which show essentially unlimited, preferably 100 % miscibility or solubility with water, and the term "limited miscibility or solubility with water" shall also include water-immiscible or water-insoluble organic solvents.

As can be seen from this section, not only is the description of such terms and solvents disclosed in Ullman's Encyclopedia specifically incorporated by reference in the instant application, but the terms are also defined in this section of the application by the Applicants. Regarding these phrases, Applicants reiterate the arguments of Response A and D, and also include the supplemental references cited in, but inadvertently not included with, Response D filed on October 23, 2002 (Chapter 6, p. 181, and Chapter 12, pp. 412-413 of Bettelheim and March's General, Organic, and Biological Chemistry, Fifth Edition; and p. 419 of Solomon's, Organic Chemistry, Sixth Edition) which support the contention that such terms are understood by those of ordinary skill in the art.

Moreover, as set forth in the Declaration of Mr. Zlatko Pflaum (one of the inventors of the presently claimed invention whose Declaration is hereinafter referred to as the "Declaration" a copy of which is attached hereto), additional arguments are presented asserting that such terms are readily understood by those of ordinary skill in the art.

For example, in paragraph 9 of the Declaration, Mr. Pflaum states that "From this disclosure [p.7] and the cited references referred to as Appendices B and C, it is clear to a

person with ordinary skill in the art which organic solvents are meant by the terms “water-miscible or water-soluble” organic solvent and which are organic solvents having “limited miscibility or solubility with water.” Such solvents are also further exemplified on page 7 of the description of the instant application and also in the reference the Ullmann’s Encyclopedia of Industrial Chemistry, Vol. A 24, cited in the description of the instant application and incorporated by reference.”

Later, Mr. Pflaum writes that “It is not necessary to list solvents, or limits of solubility, for those skilled in the art would readily understand that the solvents falling between miscible with water and immiscible with water are those which have “limited miscibility or solubility with water.” See Declaration, para. 12.

Nonetheless, as pointed out by Mr. Pflaum, “Table 16 from Ullman’s Encyclopedia *does* list solvents having limited solubility, and the Comprehensive Dictionary of Physical Chemistry provides definitions for solubility, miscibility, and the concept of two substances having solubility that is limited.” *Id.*, para. 13.

In addition, as stated above, the application itself defines these terms. Therefore, as held by Mr. Pflaum, “Based on the cited references (Appendices B-F) and the description of the instant application it can be clearly understood that the organic solvents having limited miscibility or solubility with water are those which are not miscible and/ or not soluble in water and those which are miscible and/ or soluble with water up until to a certain amount or limit.” *Id.*, para. 14.

In light of the above amendments, it is respectfully submitted that the bases for the 35 USC § 112, para. 1 and 2 rejections have been removed. Applicants respectfully submit that all claims are thus in condition for allowance.

CONCLUSION

Claims 24-46 and 48-51 have been amended to correct typographical errors, eliminate indefinite terms, and eliminate addition of new matter, as detailed above. For the reasons set forth above, it is submitted that all pending claims are in condition for allowance. Reconsideration of the claims and a notice of allowance are therefore requested.

Applicants do not believe an extension of time is required. However, in the event that an extension of time has been overlooked, Applicants submit this conditional petition for an extension of time, and request that deposit account number 19-4972 be charged for any fees that may be required for the timely consideration of this application. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

Date: November 18, 2003

Respectfully submitted,



Barbara J. Carter
Registration No. 52,703
Attorney for Applicant
Bromberg & Sunstein LLP
125 Summer Street
Boston, Massachusetts 02110-1618
Tel: (617) 443-9292
Fax: (617) 443-0004

02260/00103 280743.1